Indiana Board of Pharmacy
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Governor Mitchell E. Daniels, Jr.

July 3, 2007

John W. Rowings
Interim Director
Legislative Services Agency
Room 301
State House
Indianapolis, Indiana 46204

RE: Report to the Legislature as required by P.L.212-2005

Dear Mr. Rowings:

The 2005 Indiana General Assembly passed P.L.212-2005 (HEA 1098-2005), which was effective on July 1, 2005. According to paragraphs (b) and (c) of P.L.212-2005, SEC.79, a non-code provision, the Indiana Board of Pharmacy was authorized to establish an electronic pedigree pilot program to authenticate, track and trace drugs. The pilot program, if established, was to include all the participants of the medication supply chain from manufacturer to the end user being that of the pharmacy or practitioner. Consultation was also to have taken place with the Food and Drug Administration concerning the implementation of a mandatory electronic pedigree program.

As required, the Board conducted a study to determine whether it would be appropriate to establish an electronic pedigree pilot program to authenticate, track, and trace legend drugs. With the input of interested parties, the State Board of Pharmacy elected not to proceed with the establishment of a pilot program. The reasons for this decision are articulated below.

The State Board of Pharmacy held several meetings with the stakeholders from July 2005 through February 2007. These meetings provided opportunity for all stakeholders (Lilly, Pfizer, HDMA, NACDS, CVS, IPA, Pharma, UPS, Indiana Retail Council among others) to express concerns and provide input as to the adoption of rules for further discernment of the legislation and discussion on a pilot project for track and trace technology to be used in the passage of pedigrees. As a whole, the group felt that RFID (radio frequency identification tags) or track and trace technology was still in its infancy and could not meet the demands of a mandatory implementation across the entire supply chain. The reasons for this recommendation are listed.

1. For a pedigree to completely and continuously follow a product through the US drug supply chain, there must be agreed upon standards by all participants within the supply chain. The basic data components needed for an electronic pedigree were finally agreed upon in April of 2007 by the national coalition (EPC Global) assigned to do the task. This information is currently being evaluated and digested by the drug manufacturer and distribution community for incorporation.
2. California which had mandated the supply chain to have electronic track and trace technology on all drugs by January 1, 2007 was forced to revise its estimates due to the outcry of drug manufacturers and drug wholesalers that the 2007 date was impossible to meet. California's law

now has a proposed start date of 2009 with language that can delay it until 2011 if technology still not developed to point of massive implementation.

3. The effects of RFID technology upon a group of drugs known as biologicals is not known and is now only beginning to be studied by drug manufacturers and the FDA.
4. The FDA in their release of the 2006 Task Force Anti- Counterfeiting report stated that although they believe that electronic technology was the way to effecticiently and effectively implement pedigrees, “the pharmaceutical industry is still barely even employing the technology.” Barriers to widespread RFID adoption include costly and complicated infrastructure required to track the drugs through the distribution system, as well as the lack of any agreed-upon industry –wide standards for RFID technology.”
5. Additionally, the FDA 2006 report stated that it was not going to mandate the technology that was to be used. The FDA wanted the drug industry to use the market force to determine the best mechanism for determining and following pedigrees.
6. New authentication technologies, some currently used within the global drug distribution system, are making it more difficult for counterfeiters to replicate pharmaceuticals. Just a few of these technologies are two-D bar coding, holograms, UV markers and forensic tags. Although these technologies make it easier to tell real drug from counterfeits, the technologies must be constantly updated due to the increasing sophistication of those developing counterfeit drugs.
7. Cardinal Health performed a pilot project on RFID technology called Project Jumpstart in 2006. The pilot project examined RFID accuracy on shipments for only two products within their own facility. The pilot project demonstrated that RFID is feasible; however there is a lack of sophistication of the technology to accurately handle the thousands of products moving through the distribution system in an efficient manner. Cardinal announced plans on May 3, 2007 that it would integrate RFID technology into its California distribution system in the Fall of 2007 to prepare for the enactment of California’s pedigree legislation, but also cautioned that industry standards and technology issues need to be addressed throughout the entire supply chain, before RFID technology can be adopted industry-wide.
8. On December 1, 2006, the FDA enacted the section of the Prescription Drug Marketing Act (PDMA) of 1987 and Amendments of 1992, requiring pedigrees to be passed through the drug supply chain by non “Authorized Distributor of Record” participants in the drug distribution supply network. On December 7, 2006 a group of wholesale drug distributions successfully obtained a temporary injunction upon this requirement. As of this date, that injunction still holds. There has been no information as to when a hearing may be held to determine if the injunction will be made permanent or whether it will be overturned. If the injunction is overturned, the FDA could then enforce the PDMA pedigree requirements.

The Indiana State Board of Pharmacy is dedicated to protecting the prescription drugs that are used by the citizens of this state. The integrity of the Indiana supply chain has been greatly enhanced by the previous actions taken by the General Assembly and is viewed as a model for other states within the United States. After careful review and discussion with Indiana stakeholders, we would recommend that the enactment of an electronic pedigree be delayed The Board believes that this is still a very strong area for public concern. The Board will closely monitor the rapidly evolving technology, the drug supply chain member’s adoption of electronic and other safety measures, the FDA struggles with national pedigree enactment, and lastly the safety of the drug supply chain. It is this Board’s opinion that electronic pedigrees should be thoroughly evaluated every two years as to its place in securing Indiana’s drug supply chain for its citizens.

Sincerely,

Martin Allain
Director
Indiana Board of Pharmacy

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